DEPARTMENT OF HEALTH AND HUMAN SERVICES

1535d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 12, 2001

**VIA CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-68

John Clearly, Owner
Newman's Fish Company
2601 North Newark, Suite E
Portland, Oregon 97217

# WARNING LETTER

Dear Mr. Cleary:

We inspected your firm located at 2601 North Newark, Suite E, Portland, Oregon, on May 4, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations were presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your fresh scrombrotoxin forming species to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for refrigerated fresh scrombrotoxin forming fish to control the food safety hazards of histamines.

   This deficiency was brought to your attention in a letter dated January 9, 2001. You did not respond to this letter.

2. You must adequately monitor and record sanitation conditions and practices during processing, to comply with 21 CFR 123.11(c). Your firm was not maintaining sanitation monitoring records for the required eight areas of sanitation which are as follows:

   - Safety of water

- Condition and cleanliness of food contact surfaces
- Prevention of cross contamination
- Maintenance of hand washing, hand sanitizing, and toilet facilities
- Protection of food from adulterants
- Proper labeling, storage, and use of toxic compounds
- Control of employee health conditions
- Exclusion of pests

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: OSDA with disclosure statement